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(71) Applicant: CARDIOVASCULAR DYNAMICS, INC. [US/US]; 13700 Alton Parkway, Irvine, CA 92618 (US).

(72) Inventors: ELICKER, John; 11 Via Azur, Rancho Santa Margarita, CA 92688 (US). MILBURN, James; 12 Streamwood, Irvine, CA 92720 (US).

(74) Agent: ALTMAN, Daniel, E.; Knobbe, Martens, Olson and Bear, 16th floor, 620 Newport Center Drive, Newport Beach, CA 92660 (US).

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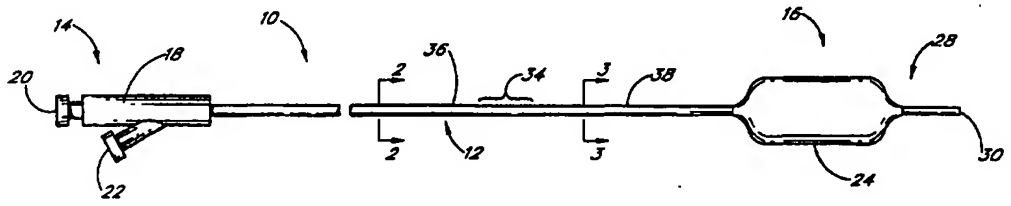

(57) Abstract

The present invention is directed toward multi-section catheters (10) having molded transition sections (34) which connect axially adjacent sections. In one preferred embodiment, a proximal catherter section (36) is joined to a distal catheter section (38). The proximal section (36) and distal sections (38) each have at least two lumen extending axially through the length of the section. The lumen (32a) in the proximal section (36) are in a side by side configuration, and the lumen (32b, 26b) in the distal section (38) are in a coaxial configuration. An injection molded transition section (34) connects the proximal section (36) to the distal section (38), so that the proximal lumen (32a, 26a) are placed in fluid communication with the distal lumen (32b, 26b) to form continuous lumen. A method of forming transition sections for use in the present invention is also disclosed.

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HYBRID CATHETER SHAFT

Background of the Invention

The present invention relates to medical catheters and, in particular, to an improved transition section between two axially adjacent sections of catheter shaft, which may be dissimilar in material or structure or both.

Various medical catheters have been developed in the prior art for percutaneous transluminal coronary or peripheral vascular applications. For example, balloon dilatation catheters for performing percutaneous transluminal coronary angioplasty ("PTCA") are well known in the art.

In addition, a variety of catheters have been developed for percutaneous transluminal placement within the arterial system for the purpose of the site-specific delivery of medication. See, for example, U.S. Patent No. 5,295,962 to Crocker, et al. Improvements to both the balloon dilatation catheters and drug delivery catheters include the provision of structures permitting continued perfusion of blood while the dilatation and/or delivery balloon is inflated. See, for example, U.S. Patent No. 5,344,402 to Crocker. Additional coronary and peripheral vascular catheters have been developed for a wide variety of diagnostic and therapeutic purposes.

In general, the catheters comprise an elongate flexible tubular body extending between a proximal control end and a distal functional end. The tubular body may have any of a variety of axial lengths, but typically ranges from about 120 cm to about 140 cm in conventional PTCA applications. At least one, and generally more, lumen extend axially from the control end of the catheter to the distal functional end, such as for conveying inflation media to inflate the balloon, medication, a guide wire, or for other purposes, depending upon the intended use of the catheter.

The outside diameter of the catheter is typically optimized between the competing interests of providing as small as possible outside diameter to enable placement of the catheter in remote narrow vessels, while at the same time providing the catheter with sufficient pushability, torquability, and the necessary functional lumen or other structures for carrying out the desired purpose. In general, PTCA catheters often have a diameter falling within the range of from about 0.030 inches to about 0.045 inches.

In general, two basic geometrical configurations for the lumen extending axially through the catheter body have been developed. Considering a two-lumen catheter body, such as a catheter having a guidewire lumen and an inflation lumen, in the first configuration the lumen extend in parallel throughout the tubular body, commonly referred to as a side-by-side configuration. In the second configuration, the two lumen are placed in a "coaxial" configuration such that an inner, generally circular, cross-sectional lumen is provided for the guidewire within a cylindrical wall, and an outer inflation lumen is defined by the space between the outer surface of the inner tubular wall and the inner surface of an outer tubular wall. Such side-by-side and coaxial lumen configurations are well known in the prior art.

For some purposes, such as to produce changes in the flexibility of the catheter or to permit reductions or other changes in the interior lumen or outside diameter of a catheter, it may become desirable to connect a first section of catheter body having a side-by-side lumen configuration to a second section of tubular body having a

coaxial lumen configuration. In addition, there may arise a need to connect two axially adjacent sections of catheter body which are formed from dissimilar materials and which may not readily bond to one another.

However, methods and structures to connect separate catheter segments are not well known in the art, and not readily producible by the conventional extrusion or other fabrication techniques typically used for the construction of tubular catheter bodies.

Thus, there remains a need for a structure and method of joining two axially adjacent catheter body sections, such that a section of catheter body having side-by-side lumen can be joined with a section of catheter body having coaxial lumen, or which allows catheter sections formed of different materials to be joined together. Preferably, the method of adjoining axially adjacent catheter body sections will provide a secure connection between the catheter body sections and produce minimal or no deviation from the desired exterior profile of the catheter body.

Summary of the Invention

The present invention is directed toward a method of joining axially adjacent catheter body sections or segments by a molding process, and to multi-section catheters which have been made in such a manner.

In one aspect, the present invention comprises a multi-section catheter having a proximal section with at least one proximal lumen extending axially therethrough. The catheter also has a distal section axially adjacent to the proximal section, and the distal section has at least one distal lumen extending axially therethrough. An injection-molded transition section connects the proximal section to the distal section, so that the proximal lumen is placed in fluid communication with the distal lumen to form a continuous lumen. Preferably, the transition section is formed, in part, by injecting a softened polymeric material into an injection-molding die containing a portion of the proximal and distal catheter sections.

In one preferred embodiment, a second proximal lumen is provided in the proximal section, and a second distal lumen is provided in the distal section, and the second proximal lumen is placed in communication with the second distal lumen within the transition section.

Advantageously, the transition section can be used to connect a proximal section having lumen in a side-by-side configuration, to a distal section having lumen in a coaxial configuration, thereby altering the geometric configuration of the lumen. Coaxial to coaxial and side by side to side by side bonding can also be readily accomplished through the method of the present invention. In addition, the transition section can be used to connect a proximal section and a distal section which are composed of different materials.

In another aspect of the present invention, there is provided a method of joining separate catheter sections to form a multi-section catheter. The first step of the method is to provide a first catheter section having at least a first lumen extending axially therethrough, and a second catheter section having at least a second lumen extending axially therethrough. The next step is to insert an end portion of a mandrel into the first and second lumen, so that the mandrel extends into the first and second lumen to form a region where the mandrel bridges a gap between the first and second catheter sections. The bridged region is then placed within a molding apparatus, and a softened polymeric material is injected into the molding apparatus. The softened polymeric material fills the gap between the first and second catheter sections, and when the softened material solidifies, the first catheter segment is bonded

to the second catheter segment. Upon removal of the mandrel, the first lumen is in fluid communication with the second lumen to form a continuous lumen.

Brief Description of the Drawings

Figure 1 is a side elevational view of an "over-the-wire" single balloon dilatation catheter incorporating the transition section of the present invention.

Figure 2 is a cross-sectional view taken along the lines 2-2 of Figure 1, showing the guidewire lumen and the inflation lumen in a side-by-side configuration.

Figure 3 is a cross-sectional view taken along the lines 3-3 of Figure 1, showing the guidewire lumen and the inflation lumen in a coaxial configuration.

Figure 4 is a schematic, partial perspective, cut-away view of the proximal side-by-side catheter segment and the distal coaxial segment positioned within the molding die with mandrels in place.

Figure 5A is a side elevational, cross-sectional view through the molding die, configured to produce a rapid-exchange embodiment, with catheter segments and mandrels in place, prior to introduction of molding material.

Figure 5B is a side elevational, cross-sectional view through the molding die of Figure 5A, after introduction of the molding material, with mandrels in place.

Figure 5C is a side elevational, cross-sectional view through the catheter of Figure 5B, after the molding die and mandrels have been removed.

Detailed Description of Preferred Embodiments

Referring to Figure 1, there is depicted a balloon dilatation catheter 10 incorporating the catheter transition section of the present invention. Although illustrated in the context of a simple balloon dilatation catheter, it is to be understood that the catheter transition section of the present invention can be readily adapted to catheters capable of any of a wide variety of functions. For example, the present inventors contemplate the use of the catheter transition section in catheters having balloon dilatation and drug-delivery capability, drug delivery alone, balloon dilatation with perfusion, balloon dilatation and drug delivery with perfusion, drug delivery with perfusion, and any other combination of functional features which may be desirable in a particular intended application. The manner of adapting the transition section of the present invention to accommodate these various functionalities will become readily apparent to those of skill in the art in view of the description which follows.

The catheter 10 generally comprises an elongate tubular flexible body 12 extending between a proximal control end 14 and a distal functional end 16. The length of the tubular body 12 depends upon the desired application. For example, lengths in the area of from about 120 cm to about 140 cm are typical for use in percutaneous transluminal coronary angioplasty applications.

In general, tubular body 12, in accordance with the present invention, has a generally circular cross-sectional configuration having an external diameter within the range of from about 0.030 inches to 0.065 inches. Alternatively, a generally triangular cross-sectional configuration can also be used, depending upon the number of lumen in the catheter, with the maximum base to apex distance also generally within the range of from about 0.030 inches to about 0.065 inches. Other noncircular configurations such as rectangular or oval may also be used.

In peripheral vascular applications tubular body 12 will typically have an outside diameter within the range of from about 0.050 inches to about 0.092 inches. In coronary vascular applications tubular body 12 will typically have an outside diameter within the range of from about 0.030 inches to about 0.045 inches.

Diameters outside the preferred range may also be used, provided that the functional consequences of the diameter are acceptable for a specified intended purpose of the catheter. For example, the lower limit of the diameter for tubular body 12 in a given application will be a function of the number of fluid or other functional lumen contained in the catheter, together with the acceptable flow rate of dilatation fluid or drugs to be delivered through the catheter. Catheters having larger tubular body diameters generally have sufficient internal flow properties and structural integrity, but reduce perfusion in the artery in which the catheter is placed. In addition, increased diameter catheter bodies tend to exhibit reduced flexibility, which can be disadvantageous in applications requiring placement of the distal end of the catheter in a remote vascular location.

In addition, tubular body 12 must have sufficient structural integrity (i.e., "pushability") to permit the catheter to be advanced to distal arterial locations without buckling or undesirable bending of the tubular body 12. The ability of tubular body 12 to transmit torque may also be desirable, such as in embodiments having drug-delivery capability on less than the entire circumference of the delivery balloon, where it may be desirable to rotate the tubular body to expose a drug infusion port on the balloon.

The proximal end 14 of the catheter 10 is provided with a manifold 18 having a plurality of access ports, as is known in the art. Generally, manifold 18 is provided with a guidewire port 20 in an over-the-wire embodiment and a balloon inflation port 22. The proximal guidewire port 20 may be eliminated in a rapid-exchange or "monorail" embodiment, in which case the proximal opening of the guidewire lumen is positioned along the tubular body 12. Additional access ports may be provided as needed, depending upon the functional capabilities of the catheter.

The distal end 16 of the catheter 10 is provided with an inflatable balloon 24, illustrated schematically in Figure 1. The inflatable balloon is in fluid communication with inflation port 22 by way of an inflation lumen 26 which extends axially within tubular body 12.

The distal end 16 of the catheter is additionally provided with an atraumatic distal tip 28, usually having a guidewire exit port 30, as is known in the art. Preferably, one or more radio opaque markers are also provided to facilitate positioning of the catheter, as is known in the art. Suitable marker bands can be produced from any of a variety of materials, including platinum, gold, and tungsten/rhenium alloy. The distal guidewire access port 30 is in communication with the proximal guidewire access port 20 in the illustrated embodiment by way of an axially extending guidewire lumen 32 which extends throughout the length of the catheter 10.

In the embodiment illustrated in Figures 1 and 2, there is provided a proximal section 36 having an inflation lumen 26a and guidewire lumen 32a arranged in a side-by-side configuration. Inflation lumen 26a and guidewire lumen 32a extend axially in side-by-side configuration along the length of proximal section 36 up to transition section 34. Referring to Figures 1 and 3, there is also provided a distal section 38 having an inflation lumen 26b and guidewire lumen 32b in coaxial configuration extending axially along the length of distal section 38 from transition section 34 to balloon 24.

In accordance with the present invention, at transition section 34, the interior lumen geometry of the embodiment depicted in Figures 1-3 is converted from the side-by-side configuration of proximal section 36 to the coaxial configuration of distal section 38. However, as will be apparent to those of skill in the art, the transition section 34 can be used to join catheter sections having a variety of different lumen and cross-sectional configurations. For example, transition section 34 may be adapted to alternatively combine a proximal coaxial section with a distal side-by-side section as well, or a proximal section with a single large drug delivery lumen with two or more smaller distal drug delivery lumen.

In a preferred embodiment of the present invention, the proximal catheter body section 36 and distal catheter body section 38 are formed from the same material. The catheter body sections 36 and 38 can be formed in accordance with any of a variety of techniques well known in the art, such as by extrusion. As can be appreciated by those of skill in the art, a number of sterilizable, flexible, medical-grade polymers well known for the construction of catheter bodies may be used to form catheter sections for use in the present invention, including medium- and high-density polyethylene, polyester, and polyurathane.

Alternatively, in certain circumstances, it may be desirable to construct a catheter in which the proximal body section 36 and distal body section 38 are formed from different materials. For example, a proximal body section comprising of polyester may in some cases be desirably bonded to a distal body section 38 comprising of polyethylene, to increase the flexibility of the catheter in the distal direction.

A further feature of the present invention is the ability of the transition section 34 to connect proximal section 36 and a distal section 38 of different outside diameters. By appropriate shaping of the mold, as will be discussed infra, the transition section 34 can be used to step from one outside diameter to another and also from one outside cross-sectional configuration to another, as may be desired.

Referring to Figure 4, there is illustrated a schematic version of one method for producing the transition section 34 in accordance with the present invention. As depicted in Figure 4, proximal section 36 features a side-by-side lumen configuration, while distal section 38 features a coaxial lumen configuration. The distal end of proximal section 36 and the proximal end of distal section 38 are illustrated in a spaced-apart orientation within a molding die 40. Prior to creation of transition section 34, a gap exists between sections 36 and 38.

A guidewire lumen supporting mandrel 42 has been removably positioned within the guidewire lumen 32 of each of the proximal and distal sections, as illustrated. In this illustration, which is configured to produce an "over-the-wire" embodiment, the proximal end of guidewire lumen mandrel 42 projects through guidewire lumen 32 to an opening in proximal section 36, such as guidewire port 20, so that mandrel 42 may be removed by withdrawal in a proximal direction following the molding step.

An inflation lumen mandrel 44 is illustrated in position within the inflation lumen 26 of each of the proximal and distal body segments 36 and 38. The inflation lumen mandrel 44 similarly extends either in a proximal or a distal direction to a point where it exits the catheter body so that it may be removed from the catheter following the molding process. In the over-the-wire setup illustrated in Figure 4, preferably both the guidewire supporting

mandrel and the inflation lumen supporting mandrel extend proximally throughout the length of the catheter and out the proximal end, so that they may be withdrawn from the control end 14 of the catheter following molding.

The guidewire lumen mandrel 42 and inflation lumen mandrel 44 preferably extend in a distal direction into distal segment 38 a sufficient distance so that the process of molding the transition section does not occlude either the guidewire lumen or inflation lumen. Preferably, the guidewire lumen mandrel and inflation lumen mandrel will extend for a distance of at least about 3cm into the distal segment 38 of the catheter.

As depicted in Figure 4, inflation lumen mandrel 44 is positioned so that it forces the centrally located coaxial guidewire lumen 32 of the distal section against the outer tubular wall of section 38. Once mandrel 44 has been removed after the molding step, however, the portion of lumen 32 distal to transition section 34 may tend to return to its centrally located coaxial configuration.

One further advantage of the transition section 34 of the present invention, as can be seen in Figure 4, is that the diameter of the inflation lumen within transition section 34 is optimized by moving the guidewire lumen wall 46 laterally so that it is adjacent the outer tubular wall 48, thereby creating the largest available space to receive the inflation lumen mandrel 44.

Following establishing the setup as illustrated in Figure 4, a suitable polymeric precursor or softened polymer is introduced into the molding die 40 to fill the gap between proximal section 36 and distal section 38. Once solidified, the polymeric material will form a secure bond between the proximal section 36 and distal section 38.

Suitable polymeric materials for use in the present invention include polyethylene, polyester and polyurathane. Moreover, when bonding sections formed of similar materials together, it is preferable to use a polymer that is similar. When bonding catheter sections formed of different materials, it is preferable to use a polymer that is similar to one of the different materials. The heating requirements and other parameters of the molding process vary from material to material, and are well known in the art.

Following introduction of the polymeric material into die 40, and cooling to a point of solidification, the molding die 40 can be opened and the resulting hybrid catheter shaft removed therefrom. The guidewire lumen mandrel 42 and inflation lumen mandrel 44 may then be removed.

Any of a variety of post-molding trimming, polishing, and other steps may then be taken, if necessary, to further optimize the characteristics of the finished hybrid catheter body.

Referring to Figures 5A-C, there is illustrated a schematic cross-sectional, elevational view of a setup used to produce a slightly more complex transition section 34 in which the outside diameter of the tubular body of the catheter steps down from a larger diameter proximal section to a smaller diameter distal section, as, for example, a 3 French diameter to a 2.5 French diameter. In addition, the setup of Figures 5A-C results in the formation of a transition section 34 which provides a guidewire aperture on the catheter tubular body to produce a "rapid exchange"-type catheter.

As depicted in Figure 5A, proximal section 36 features a dual-lumen catheter section in which the proximal lumen are in a side-by-side configuration, and the distal lumen are in a coaxial configuration. In the embodiment depicted in Figure 5A, the guidewire lumen 32 of proximal section 36 is shown filled with a stiffening wire 58, as

opposed to an open lumen. In this "rapid-exchange" embodiment, stiffening wire 58 remains in place following the molding step to add structural integrity to the proximal section 36.

Proximal section 36 and distal section 38 are shown in Figure 5A after being inserted into molding die 50. The cross-sectional area of proximal section 36 is slightly larger and often of different cross sectional configuration than that of distal section 38. In addition, the cross-sectional area of inflation lumen 26 of proximal section 36 is slightly larger than that of distal section 38. In the embodiment depicted in Figures 5A-C, molding die 50 is tapered to accommodate the differences between the proximal and distal sections. In similar fashion, molding dies of differing shapes can be provided to join a wide variety of catheter sections having differing cross-sectional areas and/or geometric configurations.

An open space 55, or "gap" exists between sections 36 and 38, as they are positioned within die 50. There is also provided on molding die 50 an injection port 52, adapted for introducing a softened polymeric material, or a polymeric precursor to the interior of die 50.

Inflation lumen mandrel 56 is illustrated in position within the inflation lumen 26 of each of the proximal and distal body sections 36 and 38. Mandrel 56 has proximal and distal sections of differing diameters, and a point 57 within die 50 where mandrel 56 steps from the larger diameter to the smaller diameter. Although not required to practice the present invention, use of a stepped diameter mandrel advantageously permits the formation of a transition section which spans a larger lumen to a smaller lumen. In addition, as will be appreciated by those of skill in the art, mandrel 56 may also be varied in shape to facilitate joining of catheter segments having lumen of differing geometric shapes.

To create a rapid exchange embodiment, it is necessary to place the guidewire entry port at some point on the catheter tubular body. For the embodiment illustrated in Figure 5A, this is achieved by using the method of the present invention to create a guidewire entry port at transition section 34. In this embodiment, a curved guidewire mandrel 54 is shown inserted into the guidewire lumen 32 of distal section 38, with the other end of mandrel 54 (not shown) extending outward from an exit port provided in molding die 50, to create the guidewire entry port after the molding process.

Referring now to Figure 5B, there is shown the setup of Figure 5A after the softened polymeric material has been introduced into port 52, and allowed to solidify. The polymeric material forms a hardened junction 58 between proximal section 36 and distal section 38, forming an exterior tubular catheter surface defined by the interior shape of the molding die.

Referring now to Figure 5C, there is shown the catheter of Figure 5B after the mandrels and molding die have been removed. As can be seen from Figure 5C, the molding process creates a transition section 34 which joins the proximal and distal inflation lumen to form a continuous inflation lumen 26. In addition, the inflation lumen 26 steps from a larger diameter in proximal section 36 to a smaller diameter in distal section 38. A guidewire entry port 60 has also been created at transition section 34, for receipt of conventional guidewires as are known in the art.

It will be appreciated that certain variations of the present invention may suggest themselves to those skilled in the art. The foregoing detailed description is to be clearly understood as given by way of illustration, the spirit and scope of this invention being limited solely by the appended claims.

WHAT IS CLAIMED IS:

1. A multi-section catheter comprising:

a proximal section having at least a first proximal lumen extending axially therethrough;

a distal section axially adjacent to the proximal section, the distal section having at least a first distal lumen extending axially therethrough;

an injection-molded transition section connecting the proximal section to the distal section, such that the first proximal lumen is placed in fluid communication with the first distal lumen to form a continuous lumen.

2. The multi-section catheter of claim 1, wherein the injection molded transition section is formed in part by injecting a softened polymeric material into an injection molding die containing a portion of the proximal and distal catheter sections.

3. The multi-section catheter of claim 1, further comprising a second proximal lumen in the proximal section, and a second distal lumen in the distal section, wherein the second proximal lumen is placed in communication with the second distal lumen within the transition section.

4. The multi-section catheter of claim 3, wherein the first and second proximal lumen are in a side-by-side configuration, and the first and second distal lumen are in a coaxial configuration.

5. The multi-section catheter of claim 4, wherein the proximal section, transition section, and distal section form an elongate tubular body, and a guidewire entry port is positioned on the tubular body.

6. The multi-section catheter of claim 1, wherein the proximal section and the distal section are composed of different materials.

7. The multi-section catheter of claim 1, wherein the distal section comprises an inflatable balloon.

8. The multi-section catheter of claim 1, wherein the distal section comprises structure capable of drug delivery to an internal body site.

9. A method of joining two separate catheter sections to form a multi-section catheter, comprising the steps of:

providing a proximal catheter section having at least a first proximal lumen extending axially therethrough;

providing a distal catheter section having at least a first distal lumen extending axially therethrough;

joining the proximal catheter section to the distal catheter section by an injection molding process, such that the first proximal lumen is placed in fluid communication with the first distal lumen.

10. The method of claim 9, wherein the first proximal lumen is in a side-by-side configuration with at least a second proximal lumen, and the first distal lumen is in a coaxial configuration with at least a second distal lumen.

11. The method of claim 10, wherein the joining step comprises:

inserting a mandrel into the first proximal and first distal lumens, so that the mandrel extends through at least a portion of the lumens and a segment of the mandrel spans the proximal and distal catheter sections;

placing the spanning mandrel segment into an injection molding apparatus;

introducing a softened polymeric material into the injection molding apparatus;

permitting the softened polymeric material to solidify, thereby bonding the proximal catheter section to the distal catheter section; and

removing the mandrel from the catheter.

12. A method of joining separate catheter segments, comprising the steps of:

providing a first catheter segment having at least a first lumen extending axially therethrough, and a second catheter segment having at least a second lumen extending axially therethrough;

inserting an end portion of a mandrel into the first and second lumen, such that the mandrel extends into the first and second lumens to form a region wherein the mandrel bridges a gap between the first and second catheter segments;

placing the bridged region within a molding apparatus;

injecting a softened polymeric material into the molding apparatus, such that the gap between the first and second catheter segments is filled by the polymeric material;

allowing the polymeric material to solidify, so that the first catheter segment is bonded to the second catheter segment, and the first lumen is in fluid communication with the second lumen to form a single continuous lumen.

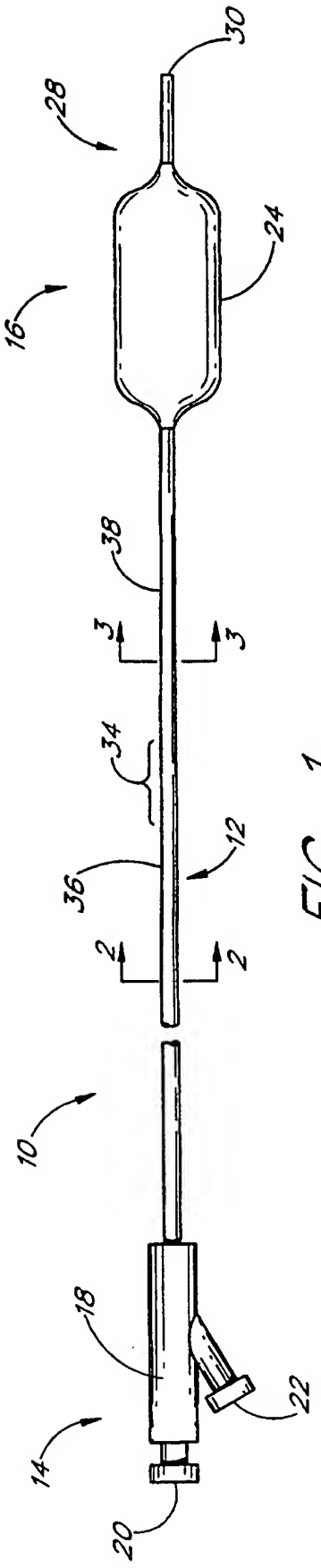

FIG. 1

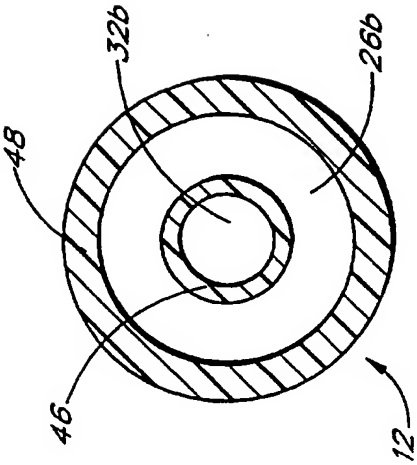

FIG. 3

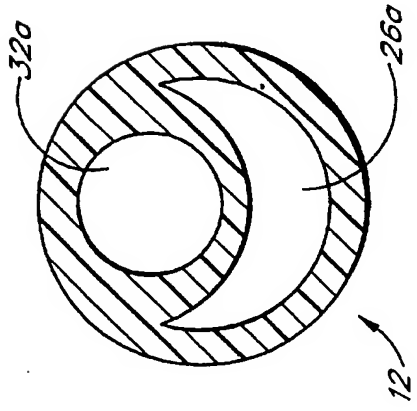

FIG. 2

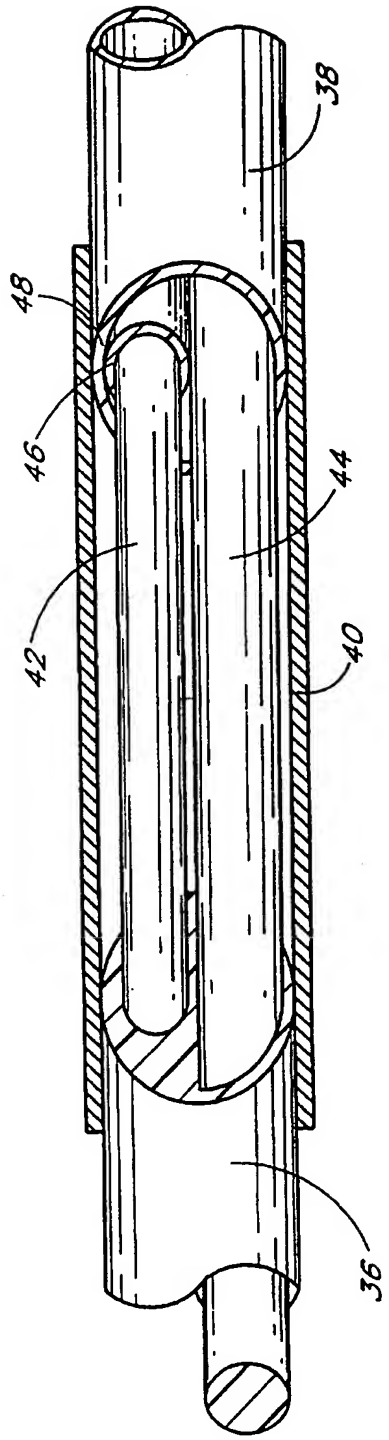

FIG. 4

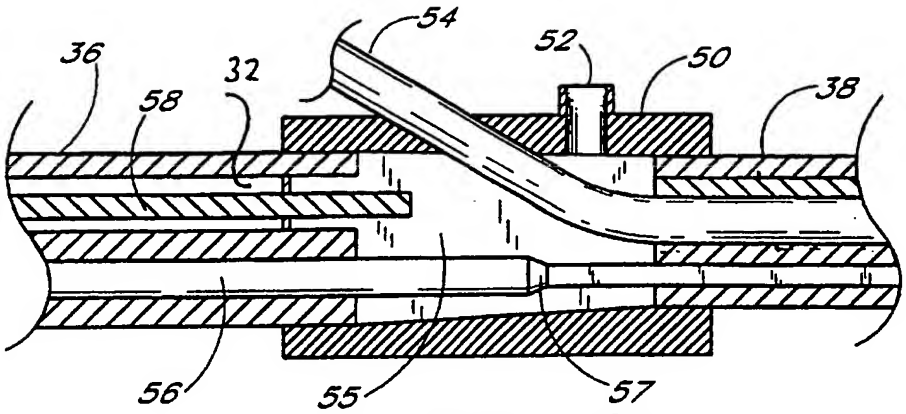

FIG. 5A

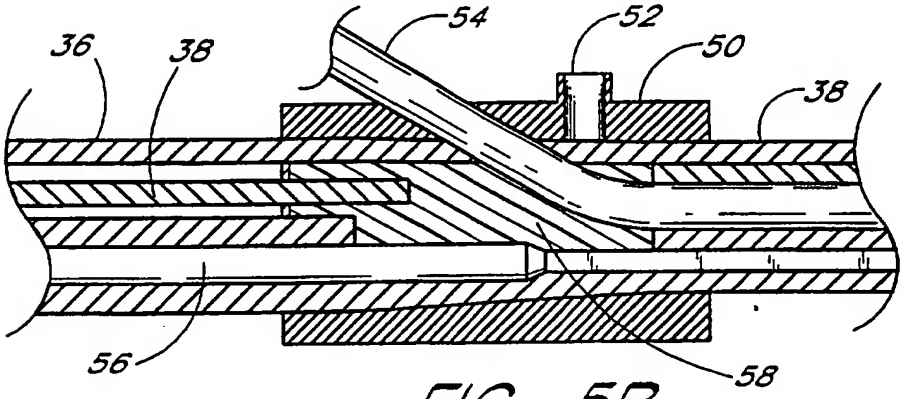

FIG. 5B

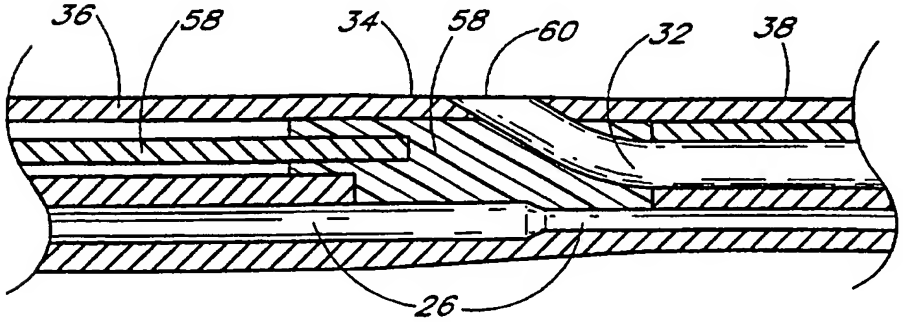

FIG. 5C

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/00922

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 25/00
US CL :604/280

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 249/83, 90, 91, 98; 264/261, 262, 277; 425/123; 604/93, 96, 103, 264, 280, 282; 606/191, 192, 194

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,261,879 A (BRILL) 17 November 1993, col. 5, lines 45-57; col. 5, lines 57-65; and col. 5, lines 52-57.	9-11
Y	US 5,324,269 A (MIRAKI) 28 June 1994, Figs. 1-10; col. 6, line 6 to col. 8, line 56.	1-7
Y	US 3,959,429 A (BENNING) 25 May 1976, col. 5, lines 55-57.	9-11
Y	US 5,238,615 A (STOOR) 24 August 1993, col. 2, line 34 to col. 4, line 4.	9-11
Y	US 5,258,157 A (NOZAKI et al) 02 November 1993, col. 3, line 46 to col. 5, line 35.	12
Y	US 4,207,900 A (PATEL et al) 17 June 1980, col. 3, line 10 to col. 7, line 4.	1-7

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)		
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed	"&"	document member of the same patent family

Date of the actual completion of the international search 11 APRIL 1997	Date of mailing of the international search report 25 APR 1997
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer CRIS L. RODRIGUEZ Telephone No. (703) 308-2194

Form PCT/ISA/210 (second sheet)(July 1992)*